Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Perseus A500
Device Model	MK06000
Serial No.	ASRJ-0197 ASRJ-0198 ASKF-0082
Manufacturer	Drägerwerk AG & Co. KGaA
Country of Origin	Germany
Reference	attached
Reason of Alert	NHRA initiates this FSN due to unexpected shutdowns of Perseus anesthesia workstations from battery failures without low battery alarms.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Tariq Pharmacy at registration.medics@intercol.com & meher.medics@intercol.com

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers of
Dräger anesthesia workstation Perseus

March 2024

Urgent Safety Notice!

Possible shutdown of Dräger anesthesia workstation Perseus
due to possible backup battery failures
Affected devices: Perseus A500 (MK06000)

Dear Sir or Madam,

Within our market surveillance activities regarding our anesthesia workstation Perseus, we became aware of a few cases in which the internal backup battery failed spontaneously while the Perseus is being operated without mains power supply. This resulted in an unexpected shutdown of the device while it was running on batteries. The affected Perseus devices started with a battery status of 100%, but quickly shut down and did not trigger the alarm for low battery. A secondary acoustic alarm signal which is independent from mains and battery power supply was generated as specified. No patient consequences have been reported to Dräger so far.

If your backup battery fails while the Perseus is being operated without mains supply, the screen goes dark and mechanical ventilation ends.
Until the device shuts down the backup battery status may be indicated as 100% and the Perseus might not generate the specified alarms for low battery prior to shutting down. In any case, the Perseus will generate a secondary acoustic alarm signal.
It will be necessary to ventilate the patient manually to prevent from serious injury or death.

To do so, you may either use an emergency ventilation bag or apply manual ventilation with the Perseus as follows:

- **adjust a suitable flow via Flow valve (Perseus devices with mechanically controlled gas mixer) or via the emergency O2 feature (Perseus device with electronically controlled gas mixer),**
- **select a suitable vaporizer concentration if applicable,**
- **adjust the APL-valve and**
- **ventilate the patient with the manual breathing bag.**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Our analyses indicate that short discharging-/charging cycles, for example caused by briefly disconnecting the device from the mains power supply repeatedly while it is on, might contribute to the observed behavior. The internal battery is designed to back up a loss of mains power supply only. Currently we are preparing a supplement to the Perseus instructions for use.

The following immediate actions need to be taken by you:

1) **Perform a short test of the battery as follows**
   (Not necessary for brand-new Perseus devices):
   - **Make sure the device has been connected to mains power supply for at least 8 hours to ensure a completely charged battery.**
   - **Disconnect mains power supply.**
   - **Operate the device in volume-controlled ventilation mode for 30 minutes with the following settings:**
     VT = 500ml / RR = 10/min / I:E = 1:1.5 / PEEP = 5mbar / FGF 10 L/min.

   The battery has successfully passed this test, if the device is operating without any battery related alarm for the entire 30 minutes. After the successful test please reconnect mains power supply.
   If the test fails, please contact your local Dräger representative to arrange replacement of the batteries before using the Perseus.

2) **Avoid short discharging/ charging cycles. Do not intentionally disconnect the Perseus from mains power supply when the device is switched on.**

   If you ensure that the device is constantly supplied with mains power while switched on, you do not need to repeat step 1.

   In any case the battery needs to be checked by a service technician during the regular inspection and safety check every 12 months.

   If you cannot ensure that the device is constantly supplied with mains power while switched on, repeat step 1 every three months.

Please ensure that all users of the Dräger Perseus devices and other persons within your organization are made aware of this information.

If you have provided the products to third parties, please forward a copy of this information.

Please keep this information at least until the supplement to the Perseus instruction for use is available.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:
According to our records, you have received Perseus devices (UDI-DI 04048675253600) manufactured by Drägerwerk AG & Co. KGaA that might be affected by this issue.

Contact:
If you have any questions, please do not hesitate to contact your local Dräger representative.
We apologize for any inconvenience caused by this measure.

With kind regards

Daniel Wolansky
Product Management
Business Unit Therapy

Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs